

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

LOUISIANA WHOLESALE DRUG CO., INC.,
On Behalf of Itself and All Others Similarly
Situating,

Plaintiffs,

v.

SANOFI-AVENTIS, SANOFI-AVENTIS U.S.
LLC, and AVENTIS PHARMACEUTICALS
INC.,

Defendants.

Civil No. 07-cv-7343 (HB)

Hon. Harold Baer, Jr., U.S.D.J.
Hon. Andrew J. Peck, U.S.M.J.
ECF Case

**PLAINTIFF LOUISIANA WHOLESALE DRUG CO. INC.'S RESPONSE TO
DEFENDANTS SANOFI-AVENTIS US LLC AND AVENTIS
PHARMACEUTICALS, INC.'S REQUEST FOR JUDICIAL NOTICE**

Defendants Sanofi-Aventis US LLC and Aventis Pharmaceuticals, Inc.

(“Defendants or Aventis”) incorrectly state that the Motion to Quash filed by non-party generic manufacturer Sandoz, Inc. (“Sandoz’s Motion”) supports their argument that Plaintiff Louisiana Wholesale Drug Co., Inc. (“Louisiana Wholesale” or “Plaintiff”) has failed to adequately allege that Aventis’ “sham” Citizen Petition caused Plaintiff’s injury.¹

Plaintiff alleges that Aventis’ Petition delayed FDA approval of **five different generic leflunomide ANDAs**, filed by five different generic manufacturers. *See* Class

¹ Louisiana Wholesale served substantively identical subpoenas for documents and deposition testimony on: (1) each of the five generic manufacturers that filed ANDAs seeking to market generic leflunomide; and (2) the generic company Defendants licensed to market an authorized generic product. With the exception of Sandoz, each of the other generic manufacturers, including Defendants’ licensee, is cooperating with Louisiana Wholesale, and is expected to begin producing responsive documents shortly.

Action Complaint ¶¶ 7, 51-66. These allegations must be taken as true on this Motion to Dismiss. Even if Sandoz's untested characterization of its own ability to receive FDA approval is taken as true (which would be improper on a motion to dismiss), Plaintiff alleges that Aventis' Citizen Petition delayed FDA approval of at least four other generic manufacturers. Plaintiff need only demonstrate that one or more of the five generic leflunomide products would have received FDA approval sooner than it actually did, had Aventis not filed its "sham" Citizen Petition. Therefore, the purported inability of one of those five generic manufacturers to have received FDA approval sooner than September 13, 2005 does not mean that Plaintiff will be unable to establish that Defendants' Petition caused the FDA to delay approval of one or more of the other four generic products. Tellingly, none of the other four generic manufacturers that Plaintiff alleges were delayed by Aventis' "sham" Citizen Petition has resisted Louisiana Wholesale's subpoena by making untested assertions about its ability to obtain FDA approval.

Defendants argue that Plaintiff has failed to adequately allege causation since Sandoz was "amending its ANDA right up to the date of FDA approval." Motion for Judicial Notice at 2. Again, Defendants misleadingly ignore that Sandoz was only one of five generic manufacturers that Plaintiff alleges were delayed from entering the leflunomide market by Defendants' "sham" Citizen Petition. Based upon the FDA approval letters attached to Defendants' Motion to Dismiss, none of the other four generic manufacturers filed amendments "right up to the date of FDA approval." In fact, generic manufacturer Barr Laboratories filed no amendments at all after Defendants filed their "sham" Citizen Petition on March 31, 2005. *See* Defendants' Motion to Dismiss

Ex. 7 at 2.² Thus, neither Sandoz's Motion, nor its ANDA arguments, renders Plaintiff's causation allegations insufficient.

Dated: December 10, 2007

By: /s/ Anne K. Fornecker
GARWIN GERSTEIN & FISHER LLP
Bruce E. Gerstein
Barry S. Taus
Anne K. Fornecker (AF-2073)
1501 Broadway, Suite 1416
New York, NY 10036
Tel.: 212-398-0055
Fax: 212-764-6620

ODOM & DES ROCHES, LLP
John Gregory Odom
Stuart E. Des Roches
Charles F. Zimmer, II
Suite 2020, Poydras Center
650 Poydras Street
New Orleans, LA 70130
Tel.: 504-522-0077
Fax: 504-522-0078

PERCY, SMITH & FOOTE, LLP
David P. Smith
W. Ross Foote
Susan C. Segura
720 Murray Street
P.O. Box 1632
Alexandria, LA 71309-1632
Tel.: 318-445-4480
Fax: 318-487-1741

² As Louisiana Wholesale explained in its Memorandum of Law in Opposition to Defendants Sanofi-Aventis US LLC and Aventis Pharmaceuticals, Inc.'s Motion to Dismiss for Failure to State a Claim ("Memo in Opposition"), the mere fact that a generic manufacturer filed an amendment to its ANDA after March 31, 2005 does not mean that these amendments caused all - - or any - - of the delay allegedly caused by the Petition. *See* Memo in Opposition at 16-17. Absent discovery, there is no way of knowing whether any of these amendments addressed issues that would have prevented FDA approval. Moreover, with the exception of Sandoz, the last amendment filed by the other four generic manufacturers was months before September 13, 2005. *See* Defendants' Motion to Dismiss Ex. 7

BERGER & MONTAGUE, P.C.

David F. Sorensen
Peter Russell Kohn
1622 Locust Street
Philadelphia, PA 19103
Tel.: 1-800-424-6690
Fax: 215-875-4604

KAPLAN, FOX & KILSHEIMER, LLP

Richard Kilsheimer
Linda Nussbaum
850 Third Avenue, 14th Floor
New York, NY 10022
Tel: 212-687-1980
Fax: 212-687-7714

KOZYAK, TROPIN &
THROCKMORTON

Adam Moskowitz
Tucker Ronzetti
2525 Ponce de Leon Blvd., 9th Floor
Miami, FL 33134
Tel.: 305-372-1800

PHELPS DUNBAR

Brent Barriere
Susie Morgan
Canal Place, Suite 2000
365 Canal Street
New Orleans, LA 70130-6534
Tel.: 504-568-1311
Fax: 504-568-9130

*Attorneys for Plaintiff Louisiana Wholesale
Drug Co., Inc.*

CERTIFICATE OF SERVICE

I, Anne K. Fornecker, do hereby certify that on December 10, 2007, I served the foregoing PLAINTIFF LOUISIANA WHOLESALE DRUG CO. INC.'S RESPONSE TO DEFENDANTS SANOFI-AVENTIS US LLC AND AVENTIS PHARMACEUTICALS, INC.'S REQUEST FOR JUDICIAL NOTICE on the following attorneys, in the manner specified below:

Via ECF Filing:

Julia E. McEvoy
Christopher R. Farrell
Rosanna K. McCalips
JONES DAY
51 Louisiana Avenue, NW
Washington DC 20001
(202) 879-3939
(202) 879-3939
(202) 626-1700
jmcevoy@jonesday.com
crrfarrell@jonesday.com
rkmccalips@jonesday.com

Samuel Joseph Hand
222 East 41st Street
JONES DAY
New York, New York 10017-6702
Tel: 212-326-3939
Fax: 212-755-7306
jhand@jonesday.com

*Attorneys for Defendants sanofi-aventis,
sanofi-aventis u.s. llc, and Aventis
Pharmaceuticals, Inc.*

KAPLAN, FOX & KILSHEIMER, LLP
Linda Nussbaum
Richard Kilsheimer
850 Third Avenue, 14th Floor
New York, NY 10022
Tel: (212) 687-1980
rkilsheimer@kaplanfox.com
lnussbaum@kaplanfox.com

KOZYAK, TROPIN & THROCKMORTON

Adam Moskowitz
Tucker Ronzetti
2525 Ponce de Leon Blvd., 9th Floor
Miami, FL 33134
Tel: (305) 372-1800
amm@kttl.com
tr@kttl.com

ODOM & DES ROCHES, LLP

John Gregory Odom
Stuart E. Des Roches
Charles F. Zimmer, II
Suite 2020, Poydras Center
650 Poydras Street
New Orleans, LA 70130
Tel: (504) 522-0077
Fax: (504) 522-0078
stuart@odrlaw.com
czimmer@odrlaw.com

*Attorneys for Plaintiff Louisiana Wholesale
Drug Co., Inc.*

Via Electronic Mail:

BERGER & MONTAGUE, P.C.

Daniel Berger
David F. Sorensen
Peter R. Kohn
1622 Locust Street
Philadelphia, PA 19103
Tel: 1-800-424-6690
Fax: (215) 875-4604
dsorensen@bm.net
pkohn@bm.net

PERCY, SMITH & FOOTE, LLP

W. Ross Foote
Susan C. Segura
720 Murray Street, P.O. Box 1632
Alexandria, LA 71309-1632
Tel: (318) 445-4480
Fax: (318) 487-1741
rfoote@psflp.com
sssegura@psflp.com

PHELPS DUNBAR
Brent Barriere
Susie Morgan
Canal Place, Suite 2000
365 Canal Street
New Orleans, LA 70130-6534
Tel: 504-568-1311
Fax: 568-9130
susie.morgan@phelps.com

*Attorneys for Plaintiff Louisiana Wholesale
Drug Co., Inc.*

/s/ Anne Fornecker

ANNE K. FORNECKER (AF-2073)
Garwin Gerstein & Fisher LLP
1501 Broadway, Suite 1416
New York, New York 10036
(Tel): 212-398-0055
(Fax): 212-764-6620
afornecker@garwingerstein.com